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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,934

02/10/2004

Bo Hansen

58610 (71432)

2105

21874

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04/17/2007

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EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/776,934

Applicant(s)

HANSEN ET AL.

Examiner

Kimberly Chong

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5-16,19-21,23-38,45,46,48-52,120-124 and 153-169 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5-16,19-21,23-38,45,46,48-52,120-124 and 153-169 is/are rejected.
- 7) ☒ Claim(s) 23-38,48 and 50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                      |                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14/04, 12/16/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>2/3/05, 8/29/05, 1/23/07.</u> <b>IDS</b> |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-87 and 120-124 and dexamethasone, in the reply filed on 01/20/2006 is acknowledged.

### ***Status of the Application***

Claims 3, 5-16, 19-21, 23-38, 45-46, 120-124, 153-169 are pending and currently under examination. Claims 1-2, 4, 17-18, 22, 39-44, 47, 53-119 and 125-152 are canceled.

### ***Drawings***

The drawings are objected to because they are not clearly labeled and a few of the drawings are dark and illegible. Figure 1 is an illustration of the different designs of the invention such as gapmers, head and tailmers and mixmers as represented in the specification at page 9, however it is not clear from Figure 1 which illustration represents head and tailmers or mixmers because only a representation of a gapmer is labeled. The specification at page 9 refers to a 'Figure 3A', but there is not a corresponding Figure 3A provided in the drawings. Figure 11 appears to represent a bar graph of LNA antisense inhibition of Survivin however the background in the graph is dark and therefore the representative bars in the graph are not clearly detectable. Figure 12 appears to represent a copy of a western blot gel but the drawing is dark and the bands in the gel are not detectable.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

### ***Substantial Duplicates***

The following claims are objected to under 37 CFR 1.75 as being substantial duplicates of each other: Claim 5 is objected to as being a substantial duplicate of claim 159. Claim 6 is objected to as being a substantial duplicate of claim 5. Claim 9 is objected to as being a substantial duplicate of claim 8. Claim 14 is objected to as being

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a substantial duplicate of claim 158. Claim 21 is objected to as being a substantial duplicate of claim 162.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Non-statutory***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 5-16, 19-21, 23-38, 45-46, 48-52, 120-124 and 153-169, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of co-pending application 11/272,124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

The instant claims are drawn to a compound consisting of 12-50 nucleotides or nucleotide analogs wherein said compound comprises a subsequence of at least 8 nucleotides or nucleotide analogs, wherein said subsequence is located within the sequence comprising SEQ ID NO. 130, wherein said nucleotide analogue is a LNA, wherein said LNA is selected from the group consisting of thio, amino or oxy-LNA, wherein said LNA is beta-D-oxy-LNA comprising phosphate or phosphorothioate linkages in various positions and a conjugate comprising said compound and at least one non-nucleotide or non-polynucleotide moiety covalently attached. The specification of the instant application discloses pharmaceutical compositions comprising said compound and a carrier, such as a taxane and further disclose a composition comprising a carrier with various pH ranges and concentrations.

Claims 1-11 of co-pending application 11/272,124 are drawn to liquid pharmaceutical composition comprising a LNA having a total of 12-2- nucleotide or nucleotide analogues comprising SEQ ID No. 28 (which is the instantly claimed SED ID No. 130). Claims 1-11 of co-pending application 11/272,124 are further drawn to said compound comprising phosphate or phosphorothioate linkages in various positions, comprising carriers of various pH ranges and concentrations.

Thus, claims 11-11 of co-pending application 11/272,124 embrace the claims of the instant application.

### ***Claim Objections***

Claims 23-38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 23-38 depend from claim 153 wherein claim 153 recites "a compound consisting of 12-50 nucleotides...". The dependent claims 23-38 recite a compound comprising nucleotides less than 12 nucleotides and the lower limit of the compound of claim 153, therefore claims 23-38 fail to further limit claim 153.

Claim 48 is objected to as being grammatically incorrect because the claim recites "The compound according claim 153". Insertion of the word "to" between according and claim would obviate this rejection.

Claim 50 recites a compound according to claim 153, wherein said subsequence comprises a stretch of 2-6 LNAs followed by a stretch of 4-12 nucleotides, which is followed by a stretch of 2-5 LNAs, which is followed by a single nucleotide. The maximum length of the subsequence of claim 153 is 16 nucleotides and the maximum length of the subsequence in claim 50 is 24 nucleotides and therefore claim 50 fails to further limit claim 153.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3, 5-16, 19-21, 23-38, 45-46, 48-52, 120-124 and 153-169 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-38 depend from claim 153 wherein claim 153 recites "a compound consisting of 12-50 nucleotides...". The dependent claims 23-38 recite a compound comprising nucleotides less than 12 nucleotides, the lower limit of the compound of claim 153, and it is therefore unclear how the compound with a lower limit of 12 nucleotides can also comprise less than 12 nucleotides.

Claim 50 recites a compound according to claim 153, wherein said subsequence comprises a stretch of 2-6 LNAs followed by a stretch of 4-12 nucleotides, which is followed by a stretch of 2-5 LNAs, which is followed by a single nucleotide. The maximum length of the subsequence of claim 153 is 16 nucleotides and the maximum length of the subsequence in claim 50 is 24 nucleotides. It is unclear how a subsequence can comprise a maximum length of 16 nucleotides and also comprise 24 nucleotides.

Claim 153 recites "wherein at least one of said nucleotides in said sequence has been replaced by a corresponding nucleotide analogue." The compound consists of 12-50 nucleotide and/or nucleotide analogues, therefore if the compound consists only of 12-50 "nucleotide analogues", then it is unclear how a "nucleotide" can be replaced with



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a nucleotide analogue given that the compound already has nucleotide analogues.

Claims 3, 5-16, 19-21, 23-38, 45-46, 48-52, 120-124 and 154-169 are rejected for being dependent on the rejected claim 153.

Claim 153 recites the limitation "said sequence". There is insufficient antecedent basis for this limitation in the claim because the claim recites a "subsequence" and does not recite a "sequence". Claims 3, 5-16, 19-21, 23-38, 45-46, 48-52, 120-124 and 154-169 are rejected for being dependent on the rejected claim 153.

Claim 154-155 recites the limitation "corresponding nucleotide". There is insufficient antecedent basis for this limitation in the claim because independent claim 153 recites a "corresponding nucleotide analogue".

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

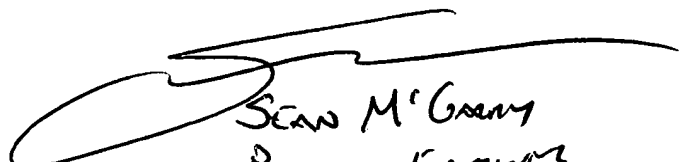
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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